# Service Manual

SIGMA 6000+
PROGRAMMABLE INFUSION PUMP
Revision 5.0 September 2001
85612

SIGMA International, Inc. 711 Park Ave, Medina, NY 14103
Phone 1-800-356-3454 Fax (716) 798-3909

# SECTION I

SIGMA International

711 Park Avenue • Medina, New York 14103-0756 • (716) 798-3901 or 1-800-356-3454 • Fax: (716) 798-3909

## LIMITED WARRANTY

SIGMA warrants, to the original purchaser, the SIGMA 6000+ Programmable Infusion Pump (herinafter pump) to be free from defects in material and workmanship under normal use and service for one year from the date of purchase. SIGMA's obligation under this limited warranty shall be limited to repair or replacement of pumps which, upon SIGMA's examination, are found to be defective in material or workmanship uner normal use and service within one year from the date of purchase by the original purchaser. The repair or replacement of any pump under this warranty shall not extend the term of this limited warranty beyond the original term as set forth in this paragraph.

All repairs qualifying under this limited warranty must be performed by qualified, trained service personnel. In the event that any pump is found to be defective during the aforesaid warranty period, the purchaser shall notify SIGMA in writing of any claimed defect within thirty days after such claimed defect is discovered. The pump claimed to be defective must them be promptly delivered to SIGMA or its designated representative for inspection and repair or replacement, if necessary. Pumps returned to SIGMA must be properly packaged and sent to SIGMA with postage and handling prepaid. Severe pump damage may result if SIGMA shipping cartons and inserts are not used. Shipping cartons and inserts are available at no charge from SIGMA.

This limited warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped pumps, misuse, abuse, improper installation, improper cleaning, alteration, or damage resulting from improper shipment to SIGMA. If, after inspection, SIGMA is unable to identify a problem, SIGMA reserves the right to invoice purchaser for such inspection.

**THIS LIMITED WARRANTY IS THE SOLE AND ENTIRE WARRANTY PERTAINING TO THE PUMP AND IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES OF ANY NATURE WHATSOEVER WHETHER EXPRESS, IMPLIED OR ARISING BY OPERATION OF LAW, TRADE, USAGE, OR COURSE OF DEALING, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. ANY AFFIRMATION OF FACT OR PROMISE MADE BY SIGMA SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO THE AFFIRMATION OR PROMISE; ANY DESCRIPTION OF THE PUMP IS FOR THE SOLE PURPOSE OF IDENTIFYING IT AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH DESCRIPTION; ANY SAMPLE OR MODEL IS FOR ILLUSTRATIVE PURPOSES ONLY AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THT THE COMP SHALL CONFORM TO THE SAMPLE OR MODEL; AND NO AFFIRMATION, PROMISE DESCRIPTION, SAMPLE OR MODEL SHALL BE DEEMED TO BE PART OF THE PURCHASE OF THE PUMP. PRUCHASER EXPRESSLY ACKNOWLEDGES THAT THIS LIMITED WARRANTY CONSTITUTES PURCHASER'S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY CLAIM OF PRUCHASER ARISING OR RESULTING DIRECTLY OR INDERECTLY FROM THE USE OF THE PUMP. IN NO EVENT SHALL SIGMA BE LIABLE HEREUNDER FOR ANY AMOUNT WHICH EXCEEDS THE PURCHASE PRICE OF THE PUMP. NO PERSON, FIRM OR CORPORATION IS AUTHORIZED TO ASSUME FOR SIGMA ANY LIABILITY IN CONNECTION WITH THE SALE OF THE PUMP.**

# TABLE OF CONTENTS

## SECTION I


Limited Warranty 1-1

Repair Authorization Policy and Field Service 1-2

Cautions and Warnings 1-5

Cleaning and Maintenance 1-6

Specifications 1-7

Compatible Administration Sets 1-8

Preventative Maintenance Procedure 1-9

Recommended Flow Rate Accuracy Test 1-13

Theory of Operation 1-14
- Mechanical Description 1-14
- Electronic Description 1-14

Test Mode Procedure 1-18

Program Options 1-20
- Keyboard Operations 1-22

Troubleshooting Guide 1-24


## SECTION II


Primary AC Schematic 2-1

Primary AC Schematic P/L 2-2

Wiring Diagram 2-3

Electrical Block Diagram 2-4

Main PC Board
- Assembly Figure 1 2-5
- Schematic, Complete 2-6
- Main CPU Circuit 2-7
- Battery Charger and Power Supply Circuit 2-8
- Axe and Battery Flag Circuit 2-9
- Motor Drive Circuit 2-10
- Flow Sensor Circuit 2-11
- Parts List Table 1 2-12

Memory Expansion PCB
- Assembly Figure 2 2-17
- Schematic 2-18
- Parts List Table 2 2-19

Display PC Board
- Assembly Figure 3 2-20
- Schematic 2-21
- Assembly (Sheet 3) 2-22
- Parts List Table 3 2-23

Final Assembly
- Parts List Table 4 2-25
- Case Removal Procedure 2-26
- Drawing Figure 4 2-27

Final Sub-Assembly
- Parts List Table 5 2-27
- Drawing Figure 5 2-29

Door Assembly
- Parts List Table 6 2-30
- Drawing Figure 6 2-31

Chassis Assembly
- Parts List Table 7 2-32
- Drawing Figure 7 2-33

Back Panel Assembly
- Parts List Table 8 2-34
- Drawing Figure 8 2-35

Bottom Support Plate Assembly
- Parts List Table 9 2-36
- Drawing Figure 9 2-37

Top Support Plate Assembly
- Parts List Table 10 2-38
- Drawing Figure 10 2-39

Front Panel Assembly
- Parts List Table 11 2-40
- Drawing Figure 11 2-41

Pump / Motor Assembly
- Parts List Table 12 2-42
- Drawing Figure 12 2-43

# TABLE OF CONTENTS

## SECTION II (con't)


Recommended Spare Parts
Parts List Table 13 2-44

Upstream Occlusion Assembly
Theory of Operation 2-45
Service Information 2-45
Drawing Figure 14 2-46
Schematic 2-47
Parts List Table 14 2-48

Temperature Compensation PCB Assembly
Drawing Figure 15 2-50
Schematic 2-51
Parts List Table 15 2-52


## SECTION III


Repair manual


All references to "AIVS – American IV Systems" are to be considered synonymous with "MPS Acacia" 3mm ID European style tubing set.

Accuracy information for 3mm ID calibrated products may vary. Contact manufacturer for device specifications.

## Repair Authorization Policy and Field Service

### Repair Authorization

Contact SIGMA International, LLC for all service information at:

Telephone: 1-800-356-3454 or (716) 789-3901
Or write: SIGMA International, LLC
711 Park Avenue
Medina, NY 14103

Email Service Coordinator at **jallport@sigmapumps.com**
Fax: (716) 798-3909

1. Please be prepared to provide the serial number, model number and description of the difficulty experienced (including all pertinent information such as flow rate, administration set used and the message displayed at the time of the difficulty.

Important: Confirm pump failure as described in this manual before return. Unconfirmed complaints are required to go through Production Testing and Quality Assurance Inspection and will be billed accordingly (see warranty).

2. Contact the SIGMA International service center as indicated above for authorization (RA) number.
3. A purchase order number or other authorized form of payment will be required on non-warranty repair before a RA number is issued.
4. If an estimate is required before work is performed, state this when you call in for a RA number.
5. Clearly reference on all applicable documents:
    a. RA number.
    b. Purchase order number.
    c. Written description of problem.
    d. Name, telephone number, e-mail and mailing address of the following people in your hospital or organization.
        - Repair service manager
        - Purchasing manager
        - Accounts payable manager

        (please note that the above information is required for both the independent biomedical service company and for the pump owner, in cases where SIGMA is not dealing directly with the pump owner)>
    e. Complete name and address
6. Package pump in the original shipping container (replacement available upon request) and affix the RA number on the outside of the package.
7. Ship pump, freight prepaid, by traceable means to: SIGMA International, LLC.
8. When a device is warranted or under service agreement, it is returned freight prepaid.

### Field Service

*Authorization:* Verbal authorization must be obtained in advance before field service can be performed. Written documentation will also be required.

*Parts:* While under warranty, SIGMA will supply factory trained/authorized service technicians with no charge parts as needed. All defective warranty parts must be returned to SIGMA.

**Please refer to the following table regarding SIGMA's non-warranty factory service repair costs.**

NON-WARRANTY FACTORY SERVICE REPAIR COSTS

| CATEGORY | DESCRIPTION | PARTS COST |
|---|---|---|
| Minimum Charge *(fixed fee) | For those parts that involve minor repairs with no parts replacement costs. | Parts at no charge as follows:<br>1. Service effective upgrades<br>2. Non-service effective upgrades preformed at the manufacturers discretion<br>3. Unconfirmed customer complaints |
| Standard Charge *(fixed fee) | For repairs of malfunctions which occurred under normal operating conditions. | Current list price |
| Maximum Charge *(fixed fee0 | For repairs made as a direct result of operational damage, improper maintenance or customer abuse. | Current list price |

*(fixed fee) – Current rates for each category listed may be obtained by contacting the SIGMA International, LLC Service Department. (1-800-356-3454)

Parts:

Replacement parts are itemized on the DOC 11060 (and if necessary DOC 11061). Each part is followed by a status code which indicates the reason for replacement, and determines if the customer will be billed for the part. Refer to the following table defining status codes:

| CATEGORY | DESCRIPTION | PARTS COST |
|---|---|---|
| A – Abuse | When a part is replaced due to customer induced operational damage (voids warranty). | List Price |
| F – Failure | When a part is replaced due to failure under normal operating conditions. | List Price |
| M – Manufacturer | When a part is replaced as a result of an inspection procedure, convenience or the manufacturer's repair process | No Charge |
| U - Update | When a part is replaced only dictated by an Engineering Change Notification (ECN). | List price only when requested by the customer, otherwise no charge. |
| P – Process | When a part is replaced only as a result of the replacement of another part | List price if repair process is due to customer induced damage, otherwise no charge. |

## STATUS CODES CONTINUED

| CATEGORY | DESCRIPTION | PARTS COST |
|---|---|---|
| PM – Preventative Maintenance | When a part is replaced for preventative maintenance (i.e. part is operational, however is degraded and may contribute to a future malfunction). | List Price |
| CR – Customer's Request | When a part is replaced per a customer request | List Price |

## Cautions and Warnings

### CAUTIONS

1. Do not immerse in liquids.

2. Periodic maintenance is needed to assure all systems are functional.

3. Solution spills should be cleaned up, as soon as possible, using a damp cloth or sponge. A cleaning disinfecting solution can be used. Wipe the front panel and the inside of the door and the area marked "AIR/DOWNSTREAM OCCL SENSOR" with water and an alcohol rinse to remove solution spillage. Dry thoroughly before use. Contact company for recommended cleaning solutions.

4. Wipe the exterior of the pump which has been dampened with the cleaning or disinfecting solution and then wipe the pump with a dry cloth to remove any excess moisture.

5. ELECTRIC SHOCK HAZARD. NO USER SERVICEABLE PARTS. DO NOT REMOVE COVER. REFERE SERVICING TO QUALIFIED SERVICE PERSONNEL.

6. FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER LICENSED PRACTITIONER.

7. CMOS electronics, used in SIGMA in fusion pumps, are prone to electrostatic damage. Service technicians should follow proper anti-static procedures when working on units. Both the bench surface and the technician should be properly grounded.

8. Before changing circuit board components, depower the unit by unplugging it from AC and disconnecting the (RED) battery lead.

9. USE ONLY I.V. ADMINISTRATION SETS THAT ARE LISTED ON THE SIGMA COMPATIBLE SET LISTING (contact SIGMA for listing). *NOTE: Use of any other sets will result in inaccuracies.*

10. Approximate battery life has not bee fully tested for continuous operational performance after unit returned to company for repair. Contact company for verification.

### WARNINGS

1. Operate on 115 volts, 60 Hz or internal battery only. Use Hospital Grade earthbound outlet for 115 volts, 60 Hz operation.

   The pump should be plugged in when stored to maintain the battery charge.

2. Do not use if room temperature is below 15.5° C (60° F) or above 40° C (104° F).

3. **DANGER – POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**

4. Do not use pens or any other sharp object to actuate switches. Replace torn or punctured membranes to assure solutions won't internally damage the membrane switch. (Replacement should only be performed by authorized personnel).

5. If using filter set, use only filters which state specifically in the instructions that they may be used with pumps. Read and follow instructions of the filter to be used.

6. Replace fluid container before it permits air to enter set tubing. If air from empty container or other source enters set, or air is detected by the pump, purge all air from set.

7. FOR CONTINUED PROTECTION AGAINST FIRE HAZARD, REPLACE FUSE ONLY WITH FUSE OF SAME TYPE AND RATING

## Cleaning and Maintenance

CAUTION:

- Always press STOP then OFF and unplug the main cord before cleaning.
- DO NOT sterilize by autoclaving or ETO gas, spray or immerse any part of the pump.
- Extended use of phenolic-based cleaners and disinfectants may cause damage to the membrane keypad.

Clean exterior surfaces with pump in upright position. Apply cleaners with a dampened cloth per manufacturers' instruction and dilution ratios. Subsequent disinfection is recommended using the same application technique. Disinfectants should remain on the pump surface in an even, but not dripping, film for the manufacturers' recommended contact time. Wipe dry or air dry after completion of contact time period before pump reuse. Dispose of all cleaning/disinfectant materials per Federal, State and Local regulations for infectious waste disposal.

*The following cleaners and disinfectants may be used:*

- 70% to 90% ethyl or isopropyl alcohol in water.*
- 10% bleach in water (produces 0.55% Sodium Hypochlorite) or a Sodium Hypochlorite cleaner disinfectant such as:

  Dispatch®** by Caltech Industries, Inc (1-800-234-7700

* Alcohols are flammable and should be used in a well-ventilated area.

** The selection and use of disinfectants should be used in accordance with hospital and user facility policies. This listing is strictly provided to indicate pump material compatibility with cleaning and disinfectant agents.

For Repair/Service, contact your local distributor or SIGMA International, LLC in the U.S.A. at 1-800-356-3454 or (716) 798-3901.

**Specifications:**

Operating Principle
Linear Peristaltic
Dimensions
9 ¾" H x 4" W x 9 ½"D
(248mm x 102mm x 241mm)
Weight
11.1 lbs. (5.0 kg)
Power Requirements
105 – 135 volts AC, 50 – 60 Hz, .05Amps
Battery Operation
*12 Volts sealed rechargeable. 3.2 amp/hr rating approximately 6hrs (5 hrs with optional upstream occlusion circuit) on fully charged new battery. (18hr charge time required).
Grounding Resistance
< 0.1 ohm
Electrical Leakage
< 15 microamp (single fault condition)
Operational Range (Rate)
0.1 – 999 ml/hr
(1 – 999 ml/hr operational setting)
Accuracy
± 5% (2 – 999 ml/hr)***
± 0.1ml (0.1 – 2.0 ml/hr)
Volume Limit Range
0.1 – 9999 ml
KVO Rate
1 ml/hr, Rate < 1ml/hr = infusion rate
Occlusion Pressure
11 ± 7 psi
Air In Line Detection
Air bubble $^{7}/_{8}$" (0.1ml) or larger
Administration Sets (Standard Administration Sets**)
Abbott (0.100" ID), Baxter ("S" suffix only), McGaw and several 3mm ID European style sets***
Alarms
Air (>.01ml); Downstream Occlusion; Check Tube; Proximal (Upstream) Occlusion (with optional Upstream Occlusion Sensor); Empty Bottle (with optional Flow Sensor); Door Open; Infusion Complete; Shut Door / Load Clip (with optional Anti-Free Flow Clip); Program Complete; Low Battery / Plug In; Rate Error; Volume Error; Flow Sensor (Program Options); Malfunctions (H/L Rate, Pump Fail, Multifail, Service Pump, Bad Prom and Bad Ram).

**UL Listed / CSA Certified**

* Pumps returned for repair have been evaluated for a minimum of 2 hours of the continuous operational performance with 18 hours of unit charge time.

** Abbott, Baxter and McGaw are registered trademarks.

*** Accuracy specifications for 3mm ID calibrated products may vary. Contact manufacturer for device specifications.

## CLEANING INTERIOR FAN

| | |
|---|---|
| Reference Drawings: | 86801 – Sub-Assembly Final |
| | 86810 – Final Assembly |
| | 87403 – Fan & Guard Assembly |
| Equipment Required: | Slot head screwdriver |
| | Phillips head screwdriver |
| | Wire tie cutter |
| | Loctite #290 |

**CAUTION:** Unit to be disconnected form AC power when servicing. Use proper static control when servicing unit.

**NOTE:** SIGMA recommended cleaning to be done at least (1) time a year or when unit is being serviced. To be done only by a qualified technician.

**PROCEDURE:** *** Reference drawing 86810 steps 1-2***

1. Remove (4) screws (Item 12) and (4) washers on case bottom and remove case (Item 9) from unit.
2. Peel back insulating sticker (Item 5) to expose Main PCB.
3. Disconnect the batter (+) positive terminal from the left side. Split the two halves apart and disconnect the (+) positive terminal on the right side.

*** Reference drawing 86801 steps 4-5***

4. Remove (2) screws (Item 37), (2) nuts (Item 36) and (2) washers (Item 35) from fan/guard assembly (Item 34) and bottom plate assembly (Item 2).
5. Remove fan/guard assembly from unit and disconnect wire connection.

*** Reference drawing 87403 steps 6-9***

6. Cut and remove wire ties (Item 3) form fan/guard assembly.
7. Remove guard and wipe clean with damp cloth.
8. Using a damp cloth, wipe the fan blades and housing. Do not immerse fan into cleaner. Wipe dry or allow to air dry prior to reinstallation.
9. Securely attach guard to fan using (2) wire ties (Item 3).

*** Reference drawing 86801 steps 10-12***

10. Connect molex connector on fan/guard assembly to connector in unit.
11. Securely attach fan/guard assembly to bottom plate assembly using (2) screws (Item 39), (2) washers (Item 35) and (2) nuts (Item 36).
12. Apply a drop of Loctite #290 to the threads of the screws.

*** Reference drawing 86810 steps 13-14***

13. Reattach battery terminals and close Main PCB and reattach insulating bag (Item 5) to unit.
14. Place case on unit and securely fasten using (4) washers (Item 13) and (4) screws (Item 12).

## COMPATIBLE ADMINISTRATION SETS

NOTE:

**Contact SIGMA for the current compatible administration set list of the specific manufacturer indicated on the labeling of your pump.**

CAUTION:

Your SIGMA pump is designed and calibrated to properly function only with compatible standard administration sets! Check the compatible manufacturer's name by observing what is specified on the top of the case or pole clamp. On older pumps you may find the manufacturer's name on the front panel.

All IV sets identified or described in each manufacturer's catalog may not be compatible with your SIGMA infusion pump.

## SIGMA 6000 IV PUMP PREVENTATIVE MAINTENANCE

Serial NO:_____ Date:_____ Customer Control NO:_____

NOTE: Recommended frequency of inspection – once annually and after any user facility maintenance.

1. *VISUAL INSPECTION*

   Inspect pump for damaged/defective components such as the membrane switch, door latch, case, door and hinges, power cord, back panel, labels and etc. NOTE: Pumps which appear to have sustained drops may have inaccurate flow rates or have faulty air/occlusion alarms due to door misalignment.

2. *MAJOR COMPONENT AND ALIGNMENT CHECK*

   a. Plug in the unit. Depress and hold numeric #9 key while depressing the ON/OFF key. The unit will display the program number "XX VX.X". Release the keys and unit will display:

      "TEST MODE"_____

   b. Press the CLEAR key and unit will display the following in sequence:

      "PROM TEST"
      "PROM OK" _____

      "RAM TEST"
      "RAM OK" _____

      "CPU TEST"
      "CPU OK" _____

      "DISP 0000"
      "DISP 1111"
      "DISP 2222"
      "DISP 3333"
      "DISP 4444"
      "DISP 5555"
      "DISP 6666"
      "DISP 7777"
      "DISP 8888"
      "DISP 9999" _____

NOTE: The brand of IV sets being used must be compatible with the pump under test. The proper set is listed within the context of a label found on either the top of the pump's case or inside its door.

The IV set must be clean and dry for testing (as well as the Air/Occlusion sensor area).

Do not stretch IV set while loading.

c. Push the PIG.RATE key and unit will display "OCC=X". Load the unit with a water filled I.V. set. The value for "X" should be between 50 and 175.

d. Remove the set from the unit. Push the VOL.LIMIT key, the unit will display "AIR=X". Load the unit with an empty I.V. set. The value for "X" should be less than 5 (<5).

e. Remove the empty set from the unit under test. Push the PIG.VOL key, unit will display "ADC=X". The value of "X" should be 0 or 1 (≤ 1).

f. Depress the RATE key; the unit will display "MOT". In approximately two minutes a number will appear. This number should match the MOT Number located on the unit calibration label within 20. The label is located on the unit bottom.

g. Exit the TEST MODE by depressing the RUN/STOP key. Turn unit off with the ON/OFF key.

3. *ALARM FUNCTIONS AND MEMORY TEST*

a. With the unit plugged in depress ON/OFF. Set the RATE to 100 and the VOL. LIMIT to 500. Turn the unit off. Turn the unit back on again. Unit should display "RATE 100". Press the VOL. LIMIT key and verify that the unit displays "VOL 500". Memory is working.

b. Load a water filled set into the unit and depress RUN/STOP key. Close the set roller clamp at a distance of 6" to 12" below the pump. "CLR OCCL" alarm shall occur within 30 seconds.

c. This test is OPTIONAL and may be preformed if specific occlusion pressures are required for facility protocol.

(Optional) Gauge Occlusion Test per step 9.

d. Push the RUN/STOP key and introduce a $^{7}/_{8}$"air bubble into I.V. line above the pump. With the unit running, a "CLR AIR" alarm shall occur as the complete air bubble passes in front of the AIR/OCCL sensor.

e. While the pump is running, unplug it from the AC outlet. The green AC indicator will turn off. The display message "BATT ON" shall be displayed alternately with the "RATE XXX" value selected.

4. *FLOW SENSOR OPERATIONS (OPTIONAL)*

   a. Attach the Flow Sensor to the drip chamber. Turn the unit on and set the program for "RATE 300" and "VOL 100". Load a set into the unit and push RUN/STOP. While the unit is running, plug in the Flow Sensor. The unit displays "IN STOP" alternately with "PUSH RUN" within 15 seconds.

   b. With the Flow Sensor plugged in, push RUN/STOP key. While the unit is running unplug the Flow Sensor. The unit displays "IN STOP" or "PROX OCCL", "EMPT BOTT", depending on the program, alternately with the "PUSH RUN" within 15 seconds.

   c. Reconnect the Flow Sensor and push RUN/STOP to continue unit operation. While the unit is running, pinch off the tubing above the unit. The unit displays "PROX OCCL" alternately with "EMPT BOTT" within 15 seconds.

5. *BATTERY LIFE TEST*

   **NOTE:** This test shall only be performed on a pump with a fully charged battery. This requires 18 consecutive hours of unit charge time.

   a. Turn the unit on and place it in the TEST MODE. Depress the PIG. RATE key for OCC function

   b. Depress the SILENCE key.

   c. Remove the unit plug from the AC outlet.

   d. Observe the time that elapses before the unit displays "PLUG IN".

   e. The required time shall be greater than:

| Pump Type | New Battery | Old Battery |
|---|---|---|
| Abbott | 4.75 hours | 2 hours |
| Baxter | 4.75 hours | 2 hours |
| McGaw | 4.25 hours | 2 hours |

6. *FLOW ACCURACY TEST*
   Reference Flow Rate Accuracy Test (Section 1 Page 13)

7. *CAM GREASE*
   Evaluate pump for excessive motor noise. Apply Dow Corning 14635 High Vacuum Grease as required to the pump cam and push rods.

8. *ELECTRICAL SAFETY CHECKS (Optional)*

This test should be performed as required and at intervals specified at your facility.

Suggested Testing

a. Leakage measurements for; grounded normal polarity and lifted neutral, both normal and reversed polarity.

Less than 25 microamps_____(single 6000)
Less than 30 microamps_____(dual 6002)
Less than 40 microamps_____(export 6000)

b. Grounding conductor resistance from safety prong to unit conductive metal case.

Less than 0.15ohms____(dual or export)
Less than 0.1ohms_____(single)

9. *GAUGE OCCLUSION TEST (Optional)*

a. Select an I.V. set of the appropriate tubing type that will provide approximately 60" of length between the bottom of the pump and the distal end of the I.V. set.

b. Load and prime the I.V. set. Attach a standard pressure gauge (30 psi 1.5%) and remove all air from the tubing and gauge. It is suggested that a three-way stopcock valve is used at the pressure gauge input.

c. Set RATE to 100 ml/hr and VOL. LIMIT to 15ml. Start the pump running.

d. After approximately 1 minute close the stopcock and allow pressure to build up between the pump and the pressure gauge.

e. Verify that the unit indicated an occlusion alarm at 11 ± 7psi.

10. *UPSTREAM OCCLUSION TEST (Optional)*

a. The solution and room temperature shall be 70°F to 80°F for this test.

b. Turn unit ON, set RATE to 5ml/hr, set VOL. LIMIT to 1ml, and CLEAR TOTAL VOL.

c. Select the proper manufacturer standard I.V. set. (DO NOT use burette, or sets that have a Y-site above the unit). Attach set to solution source and prime. Close roller clamp 12" above pump and load set into unit.

**NOTE:** It is necessary to use a new I.V. set for each unit tested (or a section of I.V. set from the closed roller clamp [12" above pump] to the bottom of the pump that has not been previously used).

d. Close door and press RUN/STOP key to start pump. The pump shall indicate "PROX OCCL" message before "RATE KVO" message. If pump fails test, contact SIGMA service department. NOTE: If "PROX OCCL" alarms within 0.2ml from start or any alarm occurs during the test, reload tubing (see NOTE above) and restart test (Unit fails if >1 of this type "PROX OCCL" alarm occurs).

## RECOMMENDED FLOW RATE ACCURACY TEST

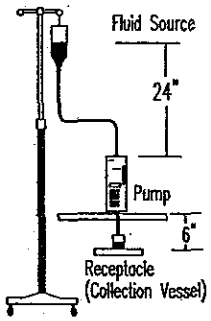
**MATERIALS REQUIRED:**

1. SIGMA 6000+ infusion pump.

2. IV set of the brand specified on the pump's label (see inside the door or top of case). Note that if pump is being accuracy tested following a clinical problem, it is essential to test with the exact IV set used when the problem occurred.

3. IV container (250, 500 or 1000ml) to be used as pumping source.

4. Collection vessel to be 100ml graduate.




**TEST DATA**

| | |
|---|---|
| Flow Rate (ml/hr) test being run at | 100 |
| Suggested collection vessel | 100ml graduate |
| Pump Vol. Limit (ml) setting during test (length of test) | 50 (30min) |
| Optimal actual volume pumped (ml) | 50ml |
| Pass Criteria: acceptable collected pumping volumes (ml) | 47.5ml – 52.5ml (± 5%) |

**Test Failed**_____ **Test Passed**_____

**PROCEDURE**

1. Hang the IV container above the pump.

2. Connect the IV set to the IV container and prime the set completely (remove all air from the tubing, be sure the drip chamber is at least half full).

3. Load the IV set into SIGMA 6000+ pump and close the pump door. Be sure all IV set clamps are open.

4. Connect the end of the IV set to the collection vessel. If vessel is a 100ml graduate, locate the end of the set at about the 55ml level. Be sure fluid is at the end of the IV set, but none has dripped into the graduate before starting the test.

5. Turn the pump on, set the flow, rate = 100 (ml/hr) and volume limit = 50ml. Begin the test by pressing the pumps' RUN key.

6. Allow the SIGMA 6000+ to pump until it goes into Infusion Complete alarm. If test is interrupted by any alarms; except air, the test can be continued as long as the pump was observed by the tester to have not been in stop for more than a few minutes, otherwise press STOP to halt the KVO (keep vein open) rate once the pump goes into Infusion Complete.

7. Observe the actual volume collected. If the collected volume is within the range 47.5ml – 52.5ml, the pump is properly calibrated. If not, return the pump to SIGMA for recalibration or follow SIGMA's Service Procedure – Flow Rate Calibration.

## THEORY OF OPERATION

The SIGMA International 6000+ is a volumetric infusion pump with optional Anti-Free Flow Clip and Upstream Occlusion Sensor devices. Volumetric implies flow rate calibration in units of known volume, ml/hr, rather than non-volumetric units of drops/min. The Anti-Free Flow Clip gives added protection against accidental free flow. The Upstream Occlusion Sensor detects occlusions (closed roller clamps) that may occur above the pump.

Pumps are generally unaffected by backpressure. They create just enough pressure to overcome the backpressure they are confronted with. This is usually less than 1 psi when infused into a vein. IF the backpressure increases, the pump's pressure increases enough to maintain the selected rate. If pressure increases to the occlusion alarm trigger point, the pump alarms and stops.

The SIGMA International 6000+ uses ultrasonic sensors for the detection of air in line and downstream occlusion pressures.

### MECHANICAL DESCRIPTION

The SIGMA 6000+ incorporates a peristaltic (tube squeezing) "finger" pump mechanism. Peristaltic should not be taken to mean non-volumetric since there are both non-volumetric (drops/min) and volumetric (ml/hr) tubing pumps.

The pump consists of a body, fingers, pressure plate and camshaft. The camshaft is driven by a stepper motor controlled by the electronic circuits. The fingers ride on the cams and are driven to produce a peristaltic motion in the pump. The tubing is squeezed between the fingers and a spring loaded pressure plate. The spring loaded pressure plate allows the pump mechanism to self adjust to the tubing size variations and variations during long term use.

The SIGMA pump incorporates an (optional) Anti-Free Flow Clip mechanism. This clip is designed to clamp the tubing closed when the set is removed from the pump to guard against accidental free flow.

SIGMA pumps are flow rate calibrated on known inner diameter (ID) tubing. The calibration principle is always the same. Flow rate is a function of both pump speed, tubing inner diameter and tubing elasticity (durometer). The electronic speed of the pump will remain with ± .1% of the selected flow rate. However, tubing variations make the overall flow rate variation somewhat greater (see specifications).

### ELECTRONIC DESCRIPTION

#### Power Supply

105-135VAC is fed through the power cord through a 1AMP fuse to a transformer. The transformer has an output of approximately 21VAC that is fed into a bridge rectifier along with a 3300uf capacitor mounted on the chassis behind the transformer. This produces 26-27VDC which is then fed to a LM317 variable voltage regulator mounted on the chassis back panel and to a battery charge circuit on the "MAIN" PCB consisting of U18 and Q8. The battery is attached to the main PCB through the 4A fuse F1.

The regulated voltage is supplied to the Chopper Drive PCB via a 4pin molex connector. R23 adjusts the regulated 13.9 VDC V+. R22 along with U18 and Q8 and their associated circuits set the battery charge voltage at 13.6VDC. Regulated V+ is supplied to the main power switch Q7, D11 and on/off latch U8. U8 is turned on or off with the ON/OFF key on the door panel which supplies a negative pulse to pin 10 of U8 when depressed. At the same time, a signal is fed back to the microprocessor via D10, U26 AND U19 telling it the ON/OFF key has been pushed.

## THEORY OF OPERATION (Continued)

### On/Off and Memory Circuits

When the ON/OFF key is pressed (assuming the unit is off), U8 pin 1 goes "HI", turning on Q4 which turns on Q7, switched +12V. This supplies the 5-volt regulators VR2 (display +V) and VR1 (logic +V). At the same time the microprocessor turns Q6 via pin 44, a latched output of U19.

When the ON/OFF key is depressed again, U8 pin 1 goes "LOW" which disables Q4. After 3 hours the microprocessor turns off Q6, which turns off Q7 (switched 12V+). This allows the retention of all settings in memory for 3 hours retention of programmed settings.

An added feature to the 6000+, which keeps the user fro accidentally turning the unit off while the pump is infusing, requires that the STOP switch must be pressed before the unit can be turned off. This feature is accomplished by the use of Q11, Q12, U17, U21, associated components and software. Using the signals from U19 pins 61 and 62, U8 pin 3 is held HIGH while the pump is running. When the pump is stopped, U8 pin 3 is allowed to go low, when the OFF key is pressed. This allows U8 pin 1 to go low, turning Q4 off.

### Microprocessor System

The heart of this unit is an RCA CDP1802 central processing unit CPU U25. It has a 2.4576Hhz external clock supplied by crystal X1. Pins 8-15 are an 8-bit data bus and pins 25-32 are address lines. C37 and R42 hold the microprocessor in a reset state via U20 pin 4 until the oscillator stabilizes for start-up.

During the main program loop the CPU outputs a stream of regular pulses from pin 17 to the gate of Q10. If the CPU locks into a loop outside the program, the pulses stop, turning Q10 on. This allows the circuit of U22, R39 and C46 to oscillate, thereby sending a negative reset pulse via U20 to pin 3 of the CPU and the AXE circuit (which will be discussed later).

Pins 21, 22, 23 and 24 are external "ON", "PLUG IN" and "LOW BATT" respectively. They are controlled by the outputs of U26 a LM3339 comparator. The input levels are adjusted with R24. The fourth flag pin 24 is used to sense a key change on the door panel membrane. Pins 33 and 34 are TPA & TPB timing pulses. Pin 7 is memory read, pin 35 is memory write and pin 36 is the interrupted input.

### Functions of the LSI Chip (U19) Interrupt Controller

The prioritization of interrupts in order highest to lowest are:

1. DOOR OPENED pin 16 – takes precedence over all other interrupts. Controlled by a hall effect switch mounted on the inside of the front door panel which is activated by a magnet in the door handle when opened.
2. LOAD CLIP pin 16 – controlled by a micro switch mounted in the housing which is activated when the clip is removed.
3. A/D OUT pin 17 – tells the microprocessor to read the A/D converter value.
4. DOOR CLOSED pin16 – controlled by a hall effect switch mounted on the inside of the front door panel which is activated by a magnet in the door handle when closed.
5. ROTATION pin 15 – this is a single pulse generated once per revolution by a hall effect switch located on the top of the pump assembly and is compared to the 8 step pulses explained in the following interrupt. If the 8 to 1 ratio isn't correct a "HI/LO" alarm occurs.
6. STEP pin 66 – this is a series of 8 pulses per revolution obtained by dividing the motor steps by 25.
7. OFF pin 13 – signals the microprocessor that the ON/OFF switch was pushed.

**Functions of the LSI Chip (U19) Interrupt Controller (Continued)**

8. DROP SENSOR pin 11 – pulses signal the microprocessor that a drop was not detected by the flow sensor (when installed).

**Other Functions**

1. CLOCK pin 22 – clock input for time control
2. Pins 61 and 62 – latched outputs control motor drive current; 43 – sensor enable; pin 67 – audio alarm activation and audio frequency; pin 64 – display blanking; and pin 44 – 3 hour memory.

**Motor Drive Circuit (Chopper Drive)**

A pulse train is emitted from LSI U19 pin 65 that is proportional to the speed at which the motor is to turn and connects to U1 pins 3 and 11 and U14 pin 1.

U1 is a 4013, dual clocked R/S latch. The signal going into pins 3 and 11 produces a two-phase signal from pins 1 and 12. This two phase signal is conditioned with "INVERTERS" from U2, "AND" gates from U3, "OR" gates from U4 and U6 and two more "D" latches from U5 to combine the original inverted clock signal from U14 pin 2 with the two phase signals to allow ½ step operation of a two phase stepper.

The signals from U19 pins 61 and 62 are motor current control signals and are used with "OR" gates from U6 to send the required signals to the motor driver IC's U7 and U12 to allow the necessary current levels to be delivered to the motor windings.

U7 and U12 are similar to switching voltage regulators in that they switch the voltage on and off rapidly to control the current drawn by the load. This switching allows more of the current to do useful work in the motor by circulating through the windings during the off cycles.

The level of current at which the switching begins is controlled by pins 9 and 7 of U7 and U12, and the voltage developed across R4 and R13 due to current drawn by the motor. The rate at which the chopping occurs is controlled by R2 and C2 for U7, and R11 and C18 for U12.

**Ultrasonic Sensor Drive**

The frequency is derived from the 2.4576Mhz crystal frequency which is fed into U19 pin 22. Here it is divided to obtain approximately 250Khz which is then used to drive the front panel sensor. This frequency output, U19 pin 43, connects to the sensor drive circuit. L1 is an inductor used to provide phase correction for the signal. C6, D5, R5, Q1, L1, R10 and SW1 select the frequency output and condition it.

**Axe Circuit**

This circuit is designed to prevent the improper operation of the pumping mechanism in the 6000+ that could result from a loop outside of the program or a failure and a subsequent lock up of the microprocessor.

In the main section of the unit's software (program), a command is inserted which causes every loop within the main program to output a signal pulse on pin 7 of U25 and the CPU. This pulse train is directed through R49 and C39 to the gate of FET Q10 which pulses it on.

**Axe Circuit (Continued)**

When Q10 is pulsed on, any charge that has accumulated on capacitor C38 due to current supplied through R38 is shorted to ground. Thus, U22 pin 1 is continuously held LO while the pulses are present at pin 17 of the CPU. The end result is: pin 3 of the CPU, the CLR pin, stays HI.

However, if the program or the microprocessor malfunctions, causing a cessation of pulse output from pin 17 of the CPU, the following events will occur:

1. The voltage on C38 rises at a rate determined by the values of R38 and C38.
2. When voltage at U22 pin 1 rises past the point where the inverter functions by driving U22 pin 2 LO, the circuit consisting of U22 pins 1 and 2, C46 and R49 begins to oscillate.
3. This changing voltage, if applied from U22 pin 2 to U20 pin 2, will function as an inverter. The inverted output is fed to a second XOR gate which also acts as an inverter; its output goes to pin 3 of the CPU. Logic LO stops and resets the microprocessor.
4. The output signal also goes to the base of Q9 through R47 and C41 switching it off. This triggers the AXE circuit.
5. When Q9 turns off (Q9 is on during normal pump operation), the voltage at the gates of Q2 and Q5 change from LO to HI, thus turning them on.
6. When Q5 turns on, it pulls the base of Q6 LO, thus turning it off.
7. When Q2 turns on, it pulls U8 pin 3 LO, turning the latch off. This sets pin 1 LO which turns off Q4. Q2 also sends a signal to the microprocessor through D9 telling it that U8 is being turned off.
8. With Q4 and Q6 both off, Q7 turns off and power to the unit shuts down.

**Display Board**

The display board consists of two 4-digit intelligent display modules, a keyboard decoder, an amplifier/demodulator for the ultrasonic receiver, a LED to indicate the unit is plugged into AC and an A/D converter for the demodulated ultrasonic signal.

The display modules are intelligent LED's that convert information from the microprocessor to a visual form. The microprocessor loads through software procedures, via the data bus, each digit with information in turn. The coding on the bus is 7 bit ASCII. There is also a blinking control to the modules tied to pin 18 of both displays. This is an active low signal supplied from U19 pin 64 on the main PCB.

IC4 on the display board is a 74C923 keyboard decoder that converts the membrane key pushed to a 5 bit hexadecimal signal and sends it to the microprocessor. When a key is pushed, a data available signal is sent to the microprocessor flag line from IC4 pin 13. When the microprocessor is ready to read the data, it sends an output (active low) to IC4 pin 12. Capacitors C1 and C2 control the keyboard scan frequency and the keyboard debounce time.

IC2 and IC3 are analog amplifiers that increase the level of the received ultrasonic signal by 100 (10x10). The output of IC2 is fed to the demodulating, voltage doubler, and then to IC1, an A/D converter. TH1, REF1 and R18 from a circuit which temperature compensates the ultrasonic sensor system.

IC1 is an 8-bit converter, controlled by the microprocessor. A signal from the microprocessor starts the conversion process at the right time, and the converter signals the microprocessor via the interrupt function when conversion is complete. The microprocessor then signals the converter to lad the voltage information to be read onto the bus.

## TEST MODE PROCEDURE

**WARNING: DO NOT PERFORM THSES CHECKS WHILE PUMP IS IN PATIENT USE**

***Summary:*** The TEST MODE enables unit readout of key numbers (voltage, etc.) and includes several automatic tests of key component functions. Covered by these tests are:

1. Display of EPROM number
2. EPROM Test
3. RAM Test
4. CPU (microprocessor) Test
5. LED (display) Test
6. Motor frequency (flow rate accuracy) readout
7. Air/Occlusion sensor voltage readout
8. Air sensor failure detection system voltage readout

Tests 2, 3, 4 and 5 are performed automatically each time the unit is turned on "cold" (off 3 hrs or more). Test 2, 4 and 5 are performed automatically with each "hot" start (off les than 3 hrs – memory still active).

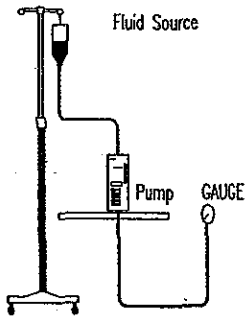
**PROCEDURE**

1. ***Test Mode Entry***
   - 2.1 Press and hold the numeric key #9, press ON. Unit will display the EPROM signature while the #9 key is pressed.
   - 2.1 EPROM number should read "XX VX.X". The X's will vary in accordance with your particular program prerequisites.
   - 2.1 Release the #9 key. The unit will display "TEST MODE".
   - 2.1 NOTE: alarms are inoperative in TEST MODE and audio beeps continually (unless SILENCE is pressed).
2. ***Key Component Test***
   - 2.1 Initiate this test by pushing CLEAR key. The following tests and related displays appear:
     - 2.1.1 "PROM TEST" – "PROM OK"
     - 2.1.2 "RAM TEST" – "RAM OK"
     - 2.1.3 "CPU TEST" – "CPU OK"
     - 2.1.4 "DISP 0000" – through "DISP 9999"
     - 2.1.5 "TEST MODE" – (Indicates this test phase is complete. "BAD PROM" etc., indicates a faulty component that needs to be replaced).
3. ***Motor Oscillator Test***
   - 3.1 Push primary RATE key.
   - 3.2 MOT = XXXX (displays after the pump motor completes 2 turns, which takes 30 – 120 seconds).
   - 3.3 1/MOT x $10^8$ = motor oscillator frequency in Hz.
     - 3.3.1 Accurate flow rates can be assumed if the MOT number is within ± 20 of the MOT number indicated on the label attached to the bottom of each unit. If the difference is greater than 20, the unit must be recalibrated. Call factory for service.
4. ***Air/Occlusion Sensor Voltage Checks***
   - 4.1 Insert air filled tubing into pump.
   - 4.2 Push VOL LIMIT key.
   - 4.3 "AIR = X" displays.
   - 4.4 Acceptable AIR range is: X <5.
   - 4.5 Insert water filled tubing into pump.
   - 4.6 Push PIG RATE key.
   - 4.7 "OCC = X" displays.
   - 4.8 Acceptable OCC range: $30 \leq X \leq 195$

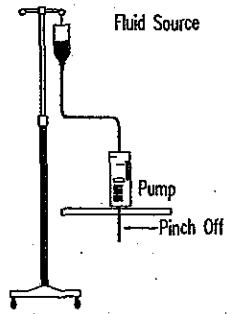
4. ***Air/Occlusion Sensor voltage Checks (continued)***

NOTE:

a. Be sure to use tubing specified for use with your unit (see front panel/case top of unit).
b. Be sure tubing in front of sensor is fresh, not worn, flat or creased.
c. Be sure unit and tubing are not cold. Unit should have been at room temperature for at least 3 hours.
d. Use at least 5 different tubes in each unit, preferably all from different lots (especially for recalibration checks). Test sets are available from SIGMA.
e. Checking occlusion function with a pressure gauge: allow for approximately 4 feet of tubing between the unit and the pressure gauge. Bleed all of the air from the line, Y-site and gauge. When the line is occluded, the displayed occlusion voltage reading should increment by at least 4 per revolution of the pump after the first occluded revolution.
f. Pinch off within 1" of the bottom of the unit will increase occlusion numbers +100 or greater within 1-2 revolutions.
g. Each change of the OCC number indicates 1 pump revolution.



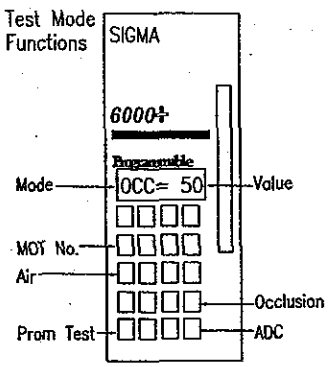

Step e




Step f

5. ***Air Sensor Failure Detection System (ADC) Check***

5.1 Push PIG VOL key.
5.2 "ADC = X" displays.
5.3 If X >4, a "PUMP FAIL" alarm will occur, when operating in a normal fashion mode (Primary, Piggyback or Program), with stops the unit after 2 revolutions.




6. Turn unit off, then back on to leave TEST MODE.

## PROGRAM OPTIONS

The SIGMA 6000+ Programmable has a number of program options which allow the Biomedical Engineer (Technician) to customize certain functions of the pump to fill the requirements of various medical departments.

Options Available:

1. Mandatory Flow Sensor
2. Total Volume Display
3. Maximum RATE and VOLUME settings.
4. Low RATE Limit
5. PIGGYBACK/PROGRAM Enable (Disable) Option

1. *Mandatory Flow Sensor*
   - 1.1 Standard Operation – The unit will allow the user the option of using or not using the Flow Sensor during infusions to detect Proximal Occlusions. In Program Mode when Flow Sensor is plugged in, the air-in-line alarm system is deactivated. Flow Sensor acts as an alternative air detection system.
   - 1.2 Mandatory Operation – If this option has been initiated, the Flow Sensor MUST be installed before the unit will start infusing. If RUN is pressed without the Flow Sensor installed unit will alarm and display "FLOW SNSR'. The unit will not start the infusion until a Flow Sensor is installed.
   - 1.3 To enable (or disable) this option, with the unit OFF, hold the #7 key down while turning the unit ON. An audible "beep" will sound when access has been completed. Release the #7 key. The display will show the present condition of the option, "SNSR OFF" (standard operation) or "SNSR ON" (mandatory operation). To toggle the option on or off, digits 3,0,3 must be pressed within 5 seconds of releasing the #7 key. After completing the selection, press OFF. This selection will remain in the non-volatile memory (battery backed RAM).

2. *Total Volume Display*
   - 2.1 Standard Operation – While infusing, the unit displays the word "RATE" (left hand display) with a rolling motion. For example: "R YYY", "RA YYY", "RAT YYY", "RATE YYY" (YYY = entered rate). The entered rate (right hand display) will stay constant.
     NOTE: If the unit is operating on battery, the "BATT ON" display will be inserted into this rate display sequence.
   - 2.2 Total Volume Operation – If this option has been initiated, the unit will insert a display of the Total Volume Infused "TOT XXXX" (XXXX = total volume infused) into the rate display sequence (section 2.1).
   - 2.3 To enable (or disable) this option, with the unit OFF, hold the #8 key down while turning the unit ON. An audible "beep" will sound when access has been completed. Release the #8 key. The display will show the present condition of the option, "TOT OFF" or "TOT ON". To toggle the condition on or off, digits 3, 0, 3 must be pressed within 5 seconds of releasing the #8 key. After completing the selection, press OFF. This will maintain the selection in the non-volatile memory (battery backed RAM).

3. *Maximum RATE and VOLUME Settings*
   - 3.1 Standard Operation – Default setting for maximum Rate is 999ml/hr and for maximum Volume is 9999ml.
   - 3.2 Maximum Settings – This option allows the Biomedical Engineer to set the maximum Rate and/or Volume. This will restrict the user from infusing too much or at too fast a Rate. If the user attempts to set the Rate or Volume above the maximum limits, the unit will alarm and display "RATE ERR" or "VOL ERR" and reset the entered parameter to 0. The lowest maximum Rate setting allowed is 20 ml/hr. The lowest maximum Volume setting allowed is 50ml.

NOTE: The maximum values set apply for all operating modes (Primary, Piggyback and Program modes).

3.3 To check or change the maximum settings, with the unit OFF, hold the #5 key down while turning the unit ON. An audible "beep" will sound when access has been completed. Release the #5 key. Within 5 seconds, enter code 3, 0, 3. The unit will then display "SET MAX".

3.3.1 To check or change the maximum Rate setting, press the primary RATE key. The unit will then display "MRAT UUU" (UUU = the present maximum rate limit). If you want to change the present setting, enter the value using the numeric portion of the keyboard. NOTE: The maximum Rate setting range is from 20ml/hr to 999ml/hr. To save the new value push the RUN/STOP switch. This will store the new value in the non-volatile memory. The unit will then "beep" and display "MRAT XXX" (XXX = new value entered).

3.3.2 To check or change the maximum Volume setting, press the primary VOL LIMIT key. The unit will then display "MVOL UUU" (UUU = the present maximum rate limit). If you want to change the present setting, enter the value using the numeric portion of the keyboard. NOTE: The maximum Rate setting range is from 50ml to 9999ml. To save the new value push the RUN/STOP switch. This will store the new value in the non-volatile memory. The unit will then "beep" and display "MVOL XXX" (XXX = new value entered).

3.3.3 After completing the check and/or change, press OFF.

4. *Low RATE limit*

4.1 Standard Operation – The Rate can be set as low as 0.1ml/hr.

4.2 Optional – The lower limit can be changed to restrict the lower limit to 1ml/hr. This means that the user cannot set the Rate any lower than 1ml/hr. The user can still use the decimal in setting a Rate larger than 1.0ml/hr (i.e. 1.1, 99.5 etc.).

4.3 To Check or change this option, with the unit OFF, hold the #4 key down while turning the unit ON. An audible "beep" will sound indicating entry into this mode. Release the #4 key. Within 5 seconds, enter code 9, 5, 1. The unit will then display "LRAT X.X" (X.X = either 0.1 or 1.0). To change the present setting, press 3, 0, 3. After completing the selection, press OFF. This will store the selection in the non-volatile memory (battery backed RAM).
NOTE: The Lower Rate Limit applies for all operating modes (Primary, Piggyback and Program mode).

5. *PIGGYBACK/PROGRAM Enable (Disable) Option*

5.1 Standard Operation – The Piggyback/Program keys can be disabled during normal pump operations.

5.2 To access option; hole the #6 key down when the pump is turned ON. A short audio "beep" will sound when operation is complete. The unit will display "PGBK ON" or "PGBK OFF" when enabled or disabled.

5.3 The option can be toggled on or off by entering the key sequence 3, 0, 3 within 5 seconds of releasing the #6 key.

5.4 "PGBK ON" – indicates Piggyback/Program keys are enabled.
"PGBK OFF" – indicates Piggyback/Program keys are disabled.

5.5 After completing the selection, press OFF. This will store the selection in the non-volatile memory (battery backed RAM).

| SIGMA 6000+ PROGRAMMABLE SPECIAL SOFTWARE FEATURE OPERATOR'S INSTRUCTIONS | | | | | | | |
|---|---|---|---|---|---|---|---|
| OPERATION | #1 START FROM | #2 HOLD DOWN | #3 PRESS & REL | WAIT FOR | ENTER CODE | TOGGLE MODE | EXTRA KEY ACTION |
| Clear Primary Settings | OFF | CLEAR | ON | "SET RATE" | | | |
| Clear Program Settings | OFF | CLEAR | ON | "SET RATE" | | | |
| Enter Program Mode | ON | PIGGY RATE | | "PROG MODE" | | Clear PRIMARY and PROGRAMMED settings prior to entering a new program. | |
| * Upper Rate Limit | OFF | #5 | ON | Beep | 3,0,3 | Push RATE ml/h | Enter new limit, push RUN |
| *Upper Volume Limit | OFF | #5 | ON | Beep | 3,0,3 | Push VOL LIMIT | Enter new limit, push RUN |
| *Lower Rate Limit | OFF | #4 | ON | Beep | 9, 5, 1 | 3, 0 3 | |
| *Total Volume Display | OFF | #8 | ON | Beep | | 3, 0 3 | |
| * Mandatory Flow Sensor (note #1) | OFF | #7 | ON | Beep | | 3, 0 3 | |
| * Turn PIG Keys On/Off (note #2) | OFF | #6 | ON | Beep | | 3, 0 3 | |
| Defeat Prox. Occlusion (note #3) | OFF | Turn ON, enter RATE and VOLUME | | "PUSH RUN" | | Push CLEAR key three times "PROX OFF" will be displayed | |
| Test Mode | OFF | #9 | ON | "XX VX.X" | | | |
| Keyboard Lock | START UP | | | Pump Running | | Push decimal (.) key twice = ON<br>Push decimal (.) key twice = OFF | |

* Program Options (set only by Bio-Technicians). For complete program description, see Service Manual section titled "Program Options".

Note 1: Applies to software versions 1.2, 1.3, 2.0, 2.1, 2.2, 3.0 & 3.2

Note2: Applies to software versions 2.0, 2.1, 2.2, 3.0, 3.2, 4.0 & 4.2

Note 3: Applies to software versions 4.0 & 4.2

## TROUBLE SHOOTING GUIDE

| PROBLEM | POSSIBLE CAUSE | CORRECTION |
|---|---|---|
| Will not turn on | a. Unit beeps once and has no display in DC | a. If unit operates correctly when plugged in, battery needs charging. Requires 18 hours for full charge. |
| | b. Faulty Membrane | b. Replace membrane switch or return unit to factory for repair. |
| | c. Internal component failure | c. Return unit to factory for repair. |
| | d. Blown AC fuse | d. Replace fuse (ref. Table 8) |
| Will not turn off | a. Faulty membrane switch | a. Disconnect the battery and replace the membrane switch or return unit to factory for repair. |
| | b. Damaged door cable | b. Disconnect the battery and return the unit to factory for repair. |
| | c. Unit still infusing | c. Push STOP, then OFF. |
| Partial or no display | a. Faulty cables or displays | a. Return unit to factory for all door, door cable and display problems. |
| Low or no battery operation | a. Unit did not have sufficient charge time | a. Unit requires 18 hours of AC after extended battery use to receive maximum charge. |
| | b. Blown battery fuse | b. Replace fuse (ref. Table 1) |
| EPROM number displays continuously | a. Faulty membrane switch | a. Disconnect the battery and replace the membrane switch or return unit to factory for repair. |
| | b. Circuit board failure | b. Return unit to factory for repair. |
| Low or no audio | a. Bad audio adjust pot | a. Replace audio pot (ref. Table 8) |
| | b. Broken wires to pot or speaker | b. Repair wires. |
| | c. Bad speaker | c. Replace speaker (ref. Table 9) |

## TROUBLE SHOOTING GUIDE (CONTINUED)

| PROBLEM | POSSIBLE CAUSE | CORRECTION |
|---|---|---|
| "SHUT DOOR" alarm | a. Door latch not completely seated.<br>b. Door latch magnet<br>c. Door sensor inop. | a. Insure door latch is fully seated.<br>b. Insure polarity correct.<br>c. Return unit to factory for repair. |
| "LOAD CLIP" alarm<br>(Optional w/Anti-Free Flow Clip) | a. Anti-free flow clip not installed.<br>b. Clip sensor inop. | a. Insure Clip is fully seated.<br>b. Return to factory for repair. |
| Constant "CLR OCCL" alarm | a. Solution spill in sensor area<br>b. Wrong IV set(s) | a. Clean sensor area and tubing in sensor area.<br>b. Check for correct manufacturer's tubing type and manual for acceptable catalog numbers. |
| Constant "CLR AIR" or nuisance air alarms or "CHK TUBE" alarm | a. Dried solution in sensor area<br>b. Wrong IV set<br>c. Pumped on section of tubing loaded in front of sensor | a. Clean sensor area with aqueous type cleaner. Remove residue with an alcohol wipe.<br>b. Check for correct manufacturer's tubing type and this manual for acceptable catalog numbers<br>c. Move IV tubing up 8" and reload fresh tubing in IV pump. |
| "PUMP FAIL" alarm | a. Excessive line noise<br>b. Electronic interference<br>c. Parts failure | a. Check AC line for noise<br>b. Move unit away from offending interference.<br>c. Return unit to factory for repair. |
| "MULT FAIL" alarm | a. Motor not running at proper rate | a. Reference "Test Mode Procedure", step #3 Motor Oscillator Test. If within specifications, return to service. If out of tolerance, return to factory. |
| "RATE ERR" alarm | a. User attempted to set RATE <1 ml/hr<br>b. User attempted to set RATE > maximum setting. | a. See "Program Options" section 4.<br>b. See "Program Options" section 3. |

## TROUBLE SHOOTING GUIDE (CONTINUED)

| PROBLEM | POSSIBLE CAUSE | CORRECTION |
|---|---|---|
| "VOL ERR" alarm | a. User attempted to set VOLUME > maximum setting | a. See "Program Options" section 3. |
| "H/L RATE" alarm | a. Magnet broken loose from the pump shaft | a. Re-glue, checking for proper polarity with door magnet (see note 1.) |
| | b. Hall effect switch failure. | b. Replace switch. |
| | c. Intermittent motor connector | c. Check for loose wires in connector jack (J4). |
| | d. Circuit board failure | d. Return unit to factory for repair. |
| | e. Broken or loose pump/motor flexible coupling | e. Replace or tighten coupling and check flow rate calibration. |
| | f. Rotation sensor housing broken loose | f. Call factory for assistance. |
| "FLOW SNSR" alarm | a. Flow Sensor not installed. | a. See "Program Options" section 1. |
| | b. Flow Sensor inoperable. | b. Call factory for assistance. |
| "PROX OCCL" alarm | a. Empty IV bottle (bag) | a. Replace IV bottle (bag). |
| | b. Upstream Occlusion | b. Insure IV tubing set is not restricted above the pump (i.e. roller clamp closed). |
| | c. J3 disconnected on Main PC Board | c. Reconnect J3. |
| | d. Circuit failure in pump | d. Return unit to factory for repair. |
| With optional Flow Sensor installed a-d above plus | e. Drop chamber overfilled | e. Insure fluid level is below the arrow on the Flow Sensor. |
| | f. Solution spill on Flow Sensor | f. With a damp cloth, wipe clean the window and emitter on the Flow Sensor. |
| | g. Flow Sensor inoperable | g. Call factory for assistance. |
| "SERV PUMP" alarm | a. Circuit board failure on Main PCB | a. Return unit to factory for repair. |

## TROUBLE SHOOTING GUIDE (CONTINUED)

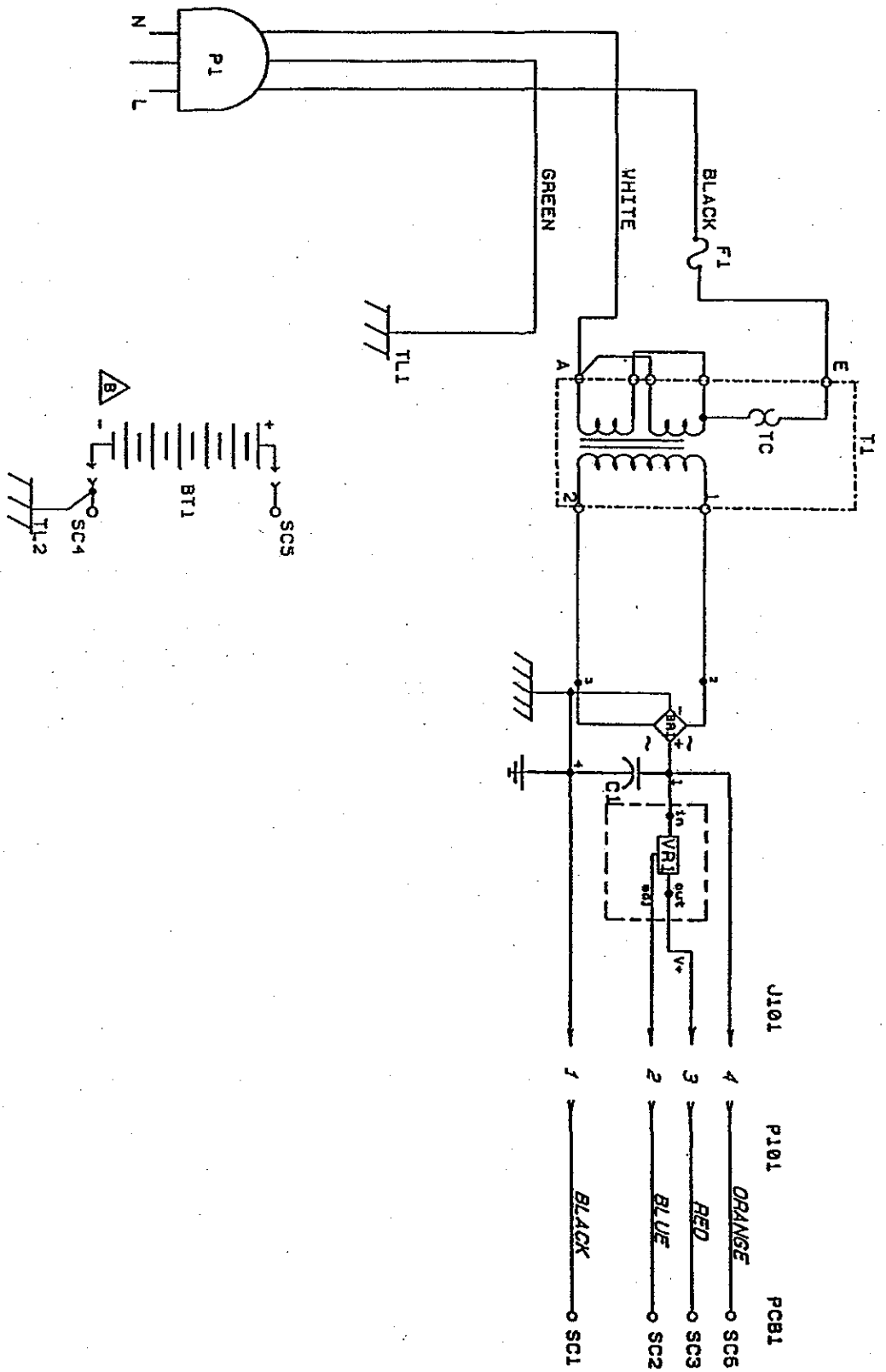
| PROBLEM | POSSIBLE CAUSE | CORRECTION |
|---|---|---|
| Flow rate inaccuracy | a. Non-compatible administration set used. | a. Obtain and verify set manufacturer and part number with compatible set list provided in this manual.<br><br>Verify IV set manufacturer with pump's calibration as indicated on the caution label. |
| | b. Administration set was utilized more than 48 hours. | b. Replace administration set. |
| | c. Clogged filter. | c. Replace administration set. |
| | d. Motor oscillating is running at wrong speed. | d. Verify MOT # in test mode with MOT # on calibration tag to be within ± 20. |
| | e. Operator error. | e. Verify reported rate, volume limit, date and time with pumps history log. (refer to "Special Software Feature Operators Instructions for History Log Access"). |
| "BAD RAM" alarm | a. Pump suffered a hardware shutdown due to both AC and DC power removed simultaneously. | a. Restore power, access test mode, turn unit off and then turn unit on. |
| | b. Pump suffered a hardware shutdown due to insufficient battery capacity during 5 min. "PLUG IN" alarm | b. Fully charge battery (18 hours on AC), access test mode, turn unit off and then turn unit on. |
| | c. Pump suffered a hardware shutdown due to an undetermined component failure | c. Trouble shoot to failed component or call factory for assistance. |

NOTE:

1. The proper polarity is indicated by the side of the magnet attracted towards the door magnet. This side of the magnet is attached to the flat side of the pump shaft (ref. Figure 12).
2. Please contact your Customer Service Representative for technical assistance.

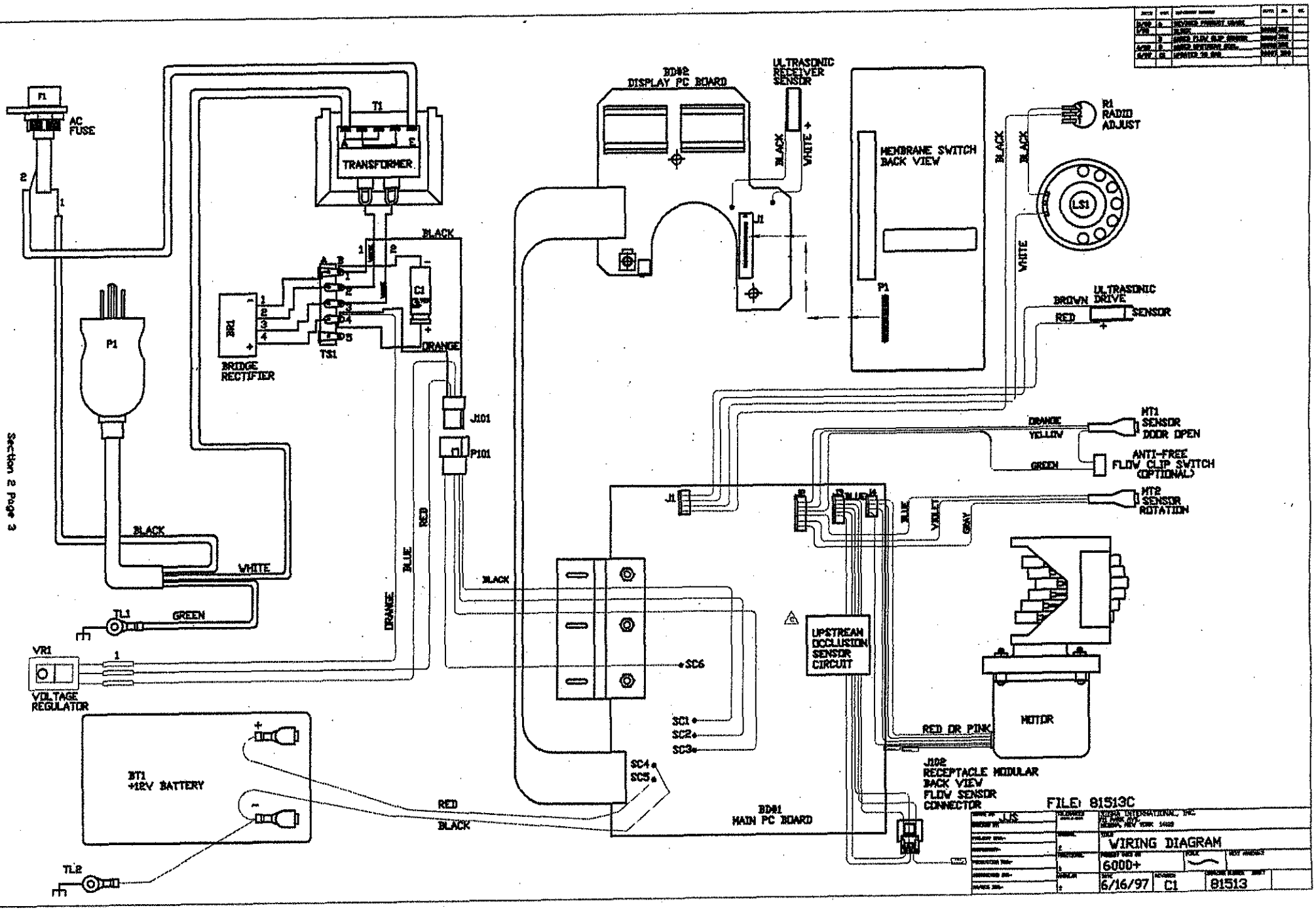
# SECTION II

Primary AC Power (120) Schematic
DWG 86433 Rev. B

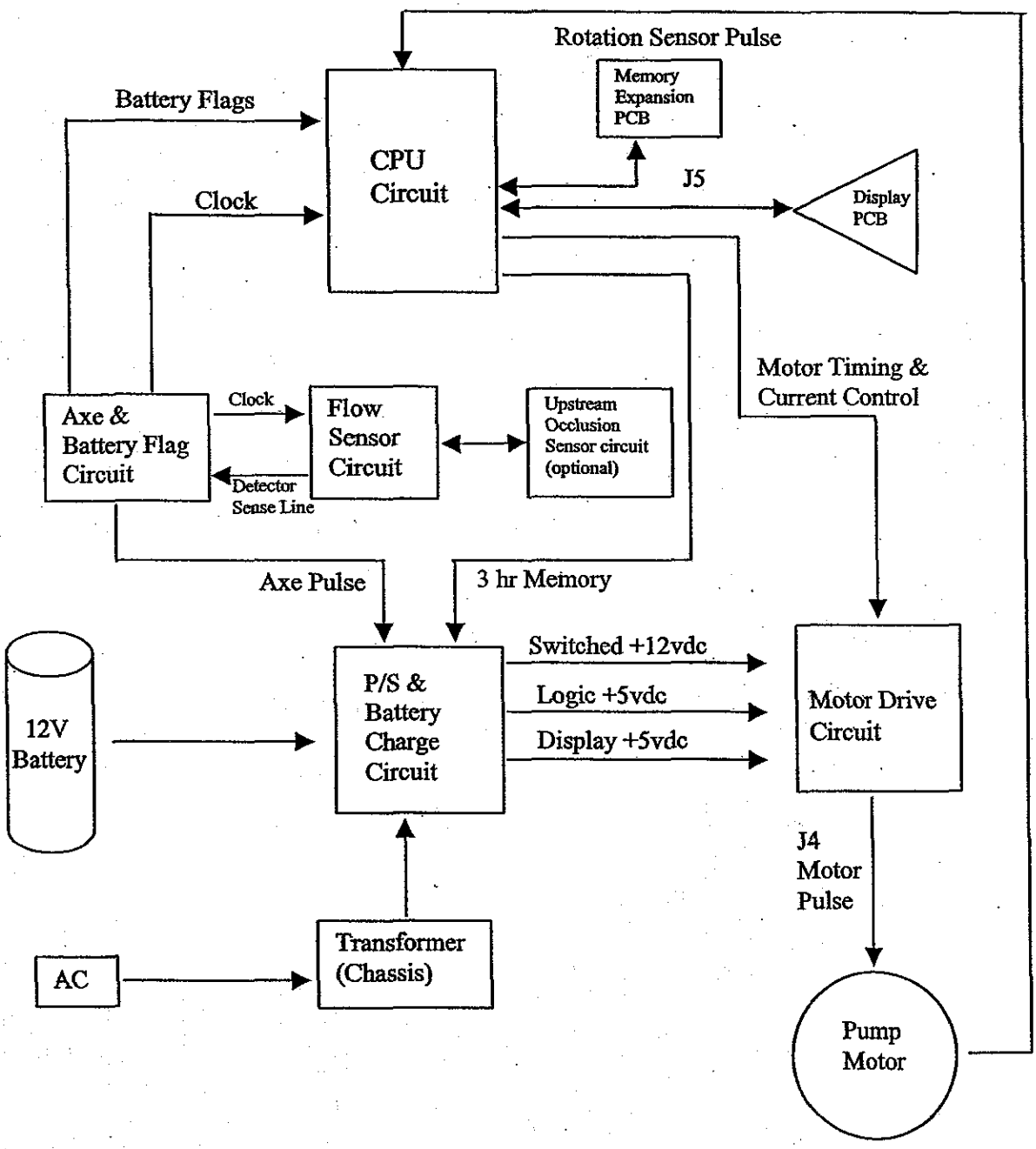


**Primary AC Power (120) Schematic, DWG 86433.**

| Designator | Description |
|---|---|
| FI | Fuse 1 amp |
| T1 | Transformer |
| TC | Thermal Cutout (part of T1) |
| BR1 | Bridge Rectifier PE05 |
| C1 | Capacitor 3300 uf, 35v |
| CR1 | Voltage regulator LM317T |
| J101 | Male Connector from Voltage Regulator Assembly |
| P101 | Female Connector to Main PC Board |
| PCB1 | PC Board, Main, Chopper Drive |
| BT1 | Battery |
| TB1 | Terminal Block |


F1
AC FUSE
T1
TRANSFORMER
BR1
BRIDGE RECTIFIER
TS1
C1
P1
J101
P101
BD#2
DISPLAY PC BOARD
ULTRASONIC RECEIVER SENSOR
MEMBRANE SWITCH BACK VIEW
J1
P1
R1
RADIO ADJUST
LS1
ULTRASONIC DRIVE
SENSOR
BROWN
RED
HT1
SENSOR
DOOR OPEN
ORANGE
YELLOW
GREEN
ANTI-FREE FLOW CLIP SWITCH (OPTIONAL)
HT2
SENSOR
ROTATION
BLUE
VIOLET
GRAY
BLACK
WHITE
RED
BLUE
ORANGE
GREEN
VR1
VOLTAGE REGULATOR
TL1
TL2
BT1
+12V BATTERY
SC1
SC2
SC3
SC4
SC5
SC6
UPSTREAM OCCLUSION SENSOR CIRCUIT
MOTOR
RED OR PINK
J102
RECEPTACLE MODULAR
BACK VIEW
FLOW SENSOR
CONNECTOR
BD#1
MAIN PC BOARD
FILE: 81513C
WIRING DIAGRAM
6000+
6/16/97
C1
81513

# Electrical Block Diagram



# Main PCB Assembly w/Cables, DWG 86626-2

## Figure 1